REMARKS

At the outset, Applicants would like to thank the Examiner Borgeest and Examiner Kemmerer for the courtesy of the Telephone Interview conducted on July 9, 2007.

Claims 80-84 and 87-98 are pending in the instant application. Claims 80-84 and 87-98 have been rejected. Claims 80 and 97 have been amended and new dependent claims 103-112 have been added. Claim 96 has been canceled in light of the amendments to claim 80 and 97 and adding of new claims 103-112. Support for these amendments is provided in claim 96 and in teachings in the specification at page 14, line 20 through page 19, line 2. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 80-84 and 87-98 under 35 U.S.C. 112, first paragraph

Claims 80-84 and 87-98 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner has acknowledged the specification to be enabling for a method of assessing skeletal muscle damage in a subject comprising detecting hypoxemia-induced skeletal troponin I (sTnI) peptide

fragment with a molecular mass of 17 kDa and/or 42 kDa covalent complex comprising sTnI with MAb C5 or a hypoxemia induced skeletal troponin T (sTnT) peptide fragment with a molecular mass of 28 kDa with MAb-JLT-12 (and antibodies disclosed in the prior art as capable of binding sTnI and sTnT) in skeletal muscle (including the diaphragm) or alternatively assessing skeletal muscle damage in a subject comprising detecting hypoxemia-induced modified sTnI having a molecular mass of 66 kDa or 26 kDa in urine. However, the Examiner suggests that the specification does not reasonably provide enablement for the claims as broadly recited.

Specifically, the Examiner suggests that there is no support in the specification for an antibody fragment capable of detecting sTnI and sTnT. As discussed during the Telephone Interview, methods for producing antibody fragments binding a selected antigen are well established. Accordingly, it was agreed that amendment of the claims to clarify that the fragment is an antigen binding fragment would address the Examiner's concern.

Thus, in an earnest effort to advance the prosecution of this case and in accordance with teachings in the specification at pages 14 through 19 and in particular page 17, lines 24-28, Applicants amended claims 80 and 97 to recite "antigen specific fragment thereof".

The Examiner also suggests that neither the specification nor the literature suggests that the claimed methods can be employed using any biological sample. Thus, as also agreed to during the Telephone Interview, Applicants have amended claims 80 and 97 to recite that the biological sample is selected from the group consisting of skeletal muscle tissue, a component of skeletal muscle tissue, blood, blood serum and urine. Support for this amendment is provided in claim 96, now canceled.

Evidence that the claimed method works in serum is provided herewith in Dr. Simpson's Declaration. See specifically paragraph 3 of Dr. Simpson's Declaration as well as Figure 1 and Figure 2 of Dr. Simpson's Declaration wherein it is demonstrated that proteolytic fragments of fsTnI were detected in serum of patients suffering from various skeletal muscle disorders using anti-TnI antibodies commercially available from Spectral Diagnostics and Hytest via the method of the instant invention.

As shown in Figure 1, detection of these proteolytic fragments was independent of creatinine kinase levels indicative of cardiac damage, thus addressing the Examiner's concerns that the method may not be specific for skeletal muscle damage. Also see paragraph 3 of Dr. Simpson's Declaration.

Figures 1 and 2 of Dr. Simpson's Declaration also provide evidence of detection of multiple additional proteolytic fragments to those exemplified in the instant application between the molecular weight of 20 and 26.6. Also see paragraph 4 of Dr. Simpson's wherein he states that as many as 7 proteolytic fragments were observed for fsTnI.

Accordingly, limitation of the claims to the exemplary peptide fragments disclosed in the instant application should not be required.

Applicants believe that the instant specification clearly teaches one of skill in the art how to make and use the invention as now claimed, thus meeting the requirements of 35 U.S.C. 112, first paragraph.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, for lack of enablement is therefore respectfully requested.

II. Provisional Obviousness-type Double Patenting Rejection

Claims 80-84 and 92-98 have been rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 16-18, 20-28, 31, 34-35 and 37-41 of copending Application No. 09/419,901. The Examiner suggests that the December 19, 2006 response did

not address this rejection. It is respectfully pointed out, however, that the December 19, 2006 reply was responsive to the Advisory Action mailed December 7, 2006 in which it was indicated that the rejection under 35 U.S.C. 102(a) and/or 35 U./S.C. 103(a) was maintained. As already argued in the response filed August 18, 2006, claims of the instant application are drawn to methods for detecting a **peptide fragment** of a myofilament protein; or a covalent or non-covalent complex of at least a **peptide fragment** of a myofilament protein and an intact myofilament protein; or two **peptide fragments** of myofilament proteins.

In contrast, claims of the copending '901 patent application are drawn to detecting a myofilament protein modification product wherein at least one myofilament protein modification product is a **chemical adduct** of a myofilament protein. Applicants believe that detection of these different products renders the instant claims patentably distinct from the pending claims of the '901 application.

Accordingly, reconsideration and withdrawal of this provisional obviousness-type double patenting rejection is respectfully requested.

With respect to the provisional obviousness-type double patenting rejection over Application No. 11/138,184, it is respectfully pointed out that the filing date for Application No. 11/138,184 is later that the instant application. Accordingly, as the term of the patent runs from the filing date of the application, it is Application No. 11/138,184 which may require a terminal disclaimer with respect to the instant application should there be overlapping claims. To date, Applicants have not received an Office Action in Application No. 11/138,184. Thus, amendments may be made to the claims in Application No. 11/138,184 which may eliminate any overlap in the claimed subject matter. Alternatively, Applicants may file a Terminal Disclaimer in Application No. 11/138,184 to address this issue.

Accordingly, withdrawal of this provisional obviousness-type double patenting rejection over Application No. 11/138,184 is also respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of December 7,

2006. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515